

AB-378U

10/698,097

REMARKS

This is a full and timely response to the non-final Official Action mailed June 13, 2005. Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Status of Claims:

By the forgoing amendment, the specification and various claims have been amended. Additionally, new claims 21-23 have been added. No original claims have been cancelled. Thus, claims 1-23 are currently pending for further action.

Prior Art Issues--Anticipation:

The outstanding Office Action rejected claims 1-4, 7, 10-12, 14, 16, 17 and 19 as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 6,205,360 to Carter et al. ("Carter"). For at least the following reasons, this rejection is respectfully traversed.

Claim 1 recites:

In a neurostimulator implant system having multiple electrode contacts through which electrical stimuli are adapted to be applied to tissue of a patient, and wherein an evoked compound action potential (ECAP) occurs in the tissue when an electrical stimulus of sufficient intensity has been applied to the tissue, and wherein the presence or absence of an ECAP in response to an applied stimulus serves as a useful objective indicator relative to the operation and functionality of the implant system, an improved method of eliciting an ECAP comprising the steps for:

- generating electrical stimuli with selectable degrees of intensity;
- delivering the electrical stimuli to at least two of the multiple electrode contacts, such that the at least two electrode contacts output an electrical current into the tissue, while gradually adjusting the intensity of the electrical stimuli and while monitoring for the occurrence of an ECAP with another separate electrode contact of the multiple electrode contacts;
- noting the intensity of the applied electrical stimuli when the ECAP is first observed;
- using the intensity of the electrical stimuli applied to the at least two electrode contacts that caused the ECAP to first occur as a guide to setting the

AB-378U

10/698,097

intensity of the electrical stimuli of the neurostimulator implant system during operation of the neurostimulator implant system.
(emphasis added).

As explained in Applicant's specification, the prior art only teaches using a single electrode to output a stimulus, with a corresponding receiving or indifferent electrode being used to complete a stimulation circuit. The prior art does not teach or suggest two or more electrodes that both "output an electrical current" as an electrical stimuli to produce an occurrence of an evoked compound action potential (ECAP).

As stated in Applicant's specification, "[t]raditional methods used to elicit the electrically-evoked compound action potential, or ECAP, deliver stimulation to a single electrode contact. There are cases where such application of a stimulus to a single electrode contact do[es] not evoke a suitable action potential." (Applicant's specification, paragraph 0003).

In contrast, Applicant has discovered that by driving two or more electrodes, either simultaneously or in rapid succession, to output an electrical current, an ECAP can be more effectively and reliably evoked. According to Applicant's specification, "electrical stimuli are applied simultaneously (or sequentially at a rapid rate) on selected small groups of electrodes while monitoring the ECAP on a nearby electrode. The presence of an observable ECAP advantageously validates operation of the implant device at a time when the patient may be unconscious or otherwise unable to provide subjective feedback." (Applicant's specification, paragraph 0024).

In the present case, Carter merely represents the prior art described by the Applicant. Specifically, Carter only teaches and suggests outputting an electrical stimulus or current with a single electrode to evoke a neural response. The current from the single output electrode completes a circuit with a second indifferent electrode to create a "channel." As explained by

AB-378U

10/698,097

Carter, "[t]he stimulations are delivered by means of a number of 'channels'. For example, the delivery of a stimulation current *between* two particular electrodes of the array may be defined as a stimulation via channel 1. Similarly other combinations of electrodes involved in stimulation delivery will also define other stimulation channels." (Carter, col. 6, lines 5-10) (emphasis added).

Thus, Carter only describes outputting a stimulus with a single output electrode, paired with an indifferent electrode, to evoke a neural response. Carter does not ever teach or suggest delivering an electrical stimuli where "at least two electrode contacts *output* an electrical current into the tissue" to evoke an ECAP as claimed. (emphasis added).

Consequently, Carter does not teach or suggest the subject matter of claim 1. Rather, Carter is merely an example of the prior art described and distinguished by Applicant. "A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least this reason, the rejection of claim 1 and its dependent claims based on Carter should be reconsidered and withdrawn.

Similarly, independent claim 10 recites:

In a neurostimulator implant system having multiple spaced-apart electrode contacts and means for delivering electrical stimuli through selected ones of the multiple electrode contacts for the purpose of stimulating tissue of a patient, an improved neurostimulator implant system adapted to elicit an evoked compound action potential (ECAP) from the tissue of the patient when an electrical stimulus of sufficient intensity is applied to the tissue, comprising:

means for generating electrical stimuli with selectable degrees of intensity;

means for delivering the electrical stimuli to at least two of the multiple electrode contacts, such that the at least two electrode contacts output an

AB-378U

10/698,097

electrical current into the tissue, while gradually adjusting the intensity of the electrical stimuli;

means for monitoring another separate electrode contact of the multiple electrode contacts for the occurrence of an ECAP, said separate electrode contact that is monitored being located near the at least two multiple electrode contacts to which the electrical stimuli is delivered;

means for noting the intensity of the applied electrical stimuli when the ECAP is first observed; and

means for using the intensity of the electrical stimuli applied to the at least two electrode contacts that caused the ECAP to first occur as a guide to setting the intensity of the electrical stimuli of the neurostimulator implant system during operation of the neurostimulator implant system.

(emphasis added).

As demonstrated above, Carter fails to teach or suggest the claimed “means for delivering the electrical stimuli to at least two of the multiple electrode contacts, such that the *at least two electrode contacts output an electrical current into the tissue.*” (emphasis added). Carter only teaches outputting a current with a single electrode contact to evoke a neural response. For at least this reason, the rejection of claim 10 and its dependent claims based on Carter should also be reconsidered and withdrawn.

Independent claim 16 recites:

A cochlear implant system comprising means for applying a stimulus pulse to at least two electrodes of multiple electrodes, either simultaneously or sequentially at a fast rate, said at least two electrodes outputting an electric current into patient tissue, in order elicit an objectively-determinable response indicative of appropriate stimulation levels for the system.

As demonstrated above, Carter fails to teach or suggest a system that comprises means for applying a stimulus pulse with at least two electrodes outputting an electric current to elicit an objectively-determinable response indicative of appropriate stimulation levels for the system. Carter only teaches outputting a current with a single electrode contact to evoke a neural response. For at least this reason, the rejection of claim 16 and its dependent claims based on Carter should also be reconsidered and withdrawn.

AB-378U

10/698,097

Prior Art Issues—Obviousness:

Dependent claims 5, 6, 8, 9, 13, 15, 18 and 20 were rejected as being unpatentable under 35 U.S.C. § 103(a) over the combined teachings of Carter and U.S. Patent No. 6,175,767 to Doyle. This rejection is respectfully traversed for at least the following reasons.

As noted above, the teachings of Carter are related to the initial process of determining appropriate stimulation parameters when setting up an implantable ear stimulator. Carter does this by evoking a neural response over a number of "channels," i.e., active and indifferent electrode pairs, to determine initial settings for the stimulator. (*See* Carter, abstract). While Doyle is also in the field of implantable ear stimulators, Doyle does not address a system or method for determining the appropriate level for stimulation parameters. Doyle is concerned with how the stimulator is operated after it has already been implanted and "fitted" or set-up for the patient.

Consequently, the teachings of Doyle are inapplicable to the teachings of Carter. One of skill in the art would readily appreciate the Doyle and Carter are addressing different things and would never have been lead to combine their teachings as proposed in the recent Office Action.

"Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed Cir. 1992)." M.P.E.P. § 2143.01 (emphasis added). For at least this additional reason, the rejection of claims 5, 6, 8, 9, 13, 15, 18 and 20, based on the erroneous combination of Carter and Doyle, should be reconsidered and withdrawn.

AB-378U

10/698,097

Double Patenting;

Lastly, the recent Office Action provisionally rejected claims 1-20 based on the judicially-created doctrine of obviousness-type double patenting in view of claims 1-6 of co-pending Application No. 10/698,098. As this is merely a *provisional* rejection, Applicant is not required to take any action in response at the present time.

If co-pending Application No. 10/698,098 should be issued prior to the present application, Applicant will consider filing a terminal disclaimer to address the double patenting issue. However, Applicant takes no position at this time as to whether the claims of the present application and those of co-pending Application No. 10/698,098 might, at some future time, present an actual double patenting issue.

AB-378U

10/698,097

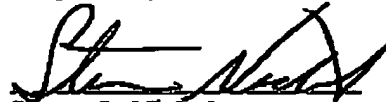
Conclusion:

The newly added claims are thought to be patentable over the prior art of record for at least the same reasons given above with respect to the original independent claims.

Therefore, examination and allowance of the newly added claims is respectfully requested.

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper that have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,



Steven L. Nichols
Registration No. 40,326

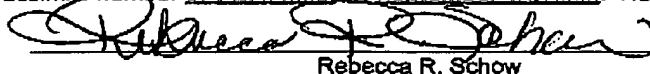
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I hereby certify that this correspondence is being transmitted to the Patent and Trademark Office facsimile number 571-273-8300 on September 12, 2005. Number of Pages: 30


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